MAY 2 1 2004

8.0 APPENDIX A: 510(K) SUMMARY

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Date Prepared: May 13, 2004

510(k) number: K041291

Applicant Information:
Kerberos Proximal Solutions, Inc.
1400 Terra Bella Ave Suite K
Mountain View, CA 94043

Contact Person: Tom Mason, VP, Regulatory Affairs and Quality Assurance
Phone Number: (650) 254-1005
FAX Number: (650) 254-1034

Device Information:
Classification: Class II
Trade Name: KPS Rinspiration™ System
Classification Name: Catheters, Intravascular, Diagnostic (21 CFR 870.1200)

Cleared Device:
The subject device is identical in intended use and method of operation to the currently cleared Rinspiration System (K031485).

Intended Use:
The KPS Rinspiration™ System is intended to infuse and aspirate in the peripheral vasculature.

Device Description:
The system consists of a Rinspiration™ Catheter and a KPS Rinspirator™ with accessories. The KPS Rinspiration™ Catheter is a multi-lumen catheter that has perforations located near the distal end of the catheter to dispense an infusible fluid. The Rinspiration™ Catheter will be placed in the peripheral vasculature of a patient over a guide wire. The catheter has a hub on the proximal end that allows access to the infusion and aspiration lumens. The KPS Rinspirator™ with accessories is a hand activated mechanical device that connects to the hub of the catheter. It allows for simultaneous irrigation and aspiration of the treatment site. The device activates two syringes for infusion and aspiration. This action is known as "Rinspiration™."

Verification Test Results:
Results of bench testing demonstrate that the KPS Rinspiration™ System is safe and effective for its intended use.

Biocompatibility:
The materials used in the KPS Rinspiration™ System have been shown to be biocompatible when tested in accordance with ISO 10993-1 Biological Evaluation of Medical Devices -- Part 1: Evaluation and testing requirements.

Summary:
Based on the intended use, product performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to currently marketed Rinspiration System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2004

Kerberos Proximal Solutions
c/o Mr. Tom Mason
1400 Terra Bella, Suite K
Mountain View, CA 94043

Re: K041291
KPS Rinspiration™ System
Regulation Number: 21 CFR 870.1200
Regulation Name: Catheter, Intravascular, Diagnostic
Regulatory Class: Class II (two)
Product Code: DQO
Dated: May 13, 2004
Received: May 14, 2004

Dear Mr. Mason:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4648. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Bachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041291

Device Name: KPS Rinspiration™ System

Indications For Use:

The KPS Rinspiration™ System is intended to infuse and aspirate in the peripheral vasculature.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Lechner

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041291